Docket No. CV0326

## **REMARKS**

The pending Office Action has been carefully considered. Eighteen claims are pending in this application, numbered 1, 3, 5-18, 21 and 22. Claim 1 is the sole independent claim. Claims 1 and 22 have been amended.

The Examiner rejected the formerly pending claims in view of the references referred to herein as Doyle, Steer, Hahn and Lloyd.

The pending claims are neither anticipated by nor rendered obvious, under 35 USC 102 or 103, respectively, in view of the references cited, applied singly or in combination.

Doyle (commonly assigned with the present application) discloses a medical grade pressure sensitive adhesive composition that shows resistance to biological fluids. Steer (also commonly assigned herewith) discloses a mechanical interlocking coupling for a two-piece ostomy system. Hahn discloses a polyorganosiloxane pressure sensitive adhesive. Lloyd discloses a one piece ostomy device that attaches directly to the skin of a person having an ostomy, referred to herein as an ostomate.

The present invention is a two component ostomy device. The two components, a body attaching wafer and a pouch, couple to each other adhesively. These components couple along a solvent-free, pressure sensitive adhesive interface between the two components. They also separate along the interface.

The references cited by the Examiner do not teach a two piece ostomy system that couple along a solvent-fee adhesive interface. Steer teaches a two-piece mechanical coupling and Doyle teaches a one piece ostomy device or pouch that adhesively attaches to the ostomate's skin. There is no teaching of a

Docket No. CV0326

solvent-fee adhesive interface along which a two component ostomy system couples and separates.

The present invention as claimed has a solvent-free adhesive interface coated onto a surface of at least one of the two components. The adhesive interface includes one or more polysiloxanes or one or more polysiloxanes and at least one silicate resin including their blends and reaction products. This polysiloxane adhesive interface is solvent-free, resealable and resistant to migration of stomal fluids into the interface.

Furthermore, according to the present invention as claimed one of the two components has a closed cell foam surface and the other component has a surface on the other side of the adhesive interface. The solvent-free polysiloxane adhesive interface is coated onto at least one of the two surfaces on the opposite sides of the adhesive interface.

The Examiner cites Lloyd in support of the arguments that the prior art teaches a closed cell foam surface and an adhesive interface coated onto the foam surface. The Examiner makes reference to closed cell foam surface 3 and adhesive interface 4 in Figures 1 and 2 of Lloyd.

Lloyd is a one component device. The pouch has a foam surface with an adhesive on it that attaches directly to the skin of the ostomate.

Foam on a one piece device does not teach or suggest a two piece adhesive coupling having an adhesive interface along which the two components are coupled and separated. The foam surface of the present invention does not attach to skin as taught by Lloyd. The adhesive interface of the present invention as claimed is located and functions in a manner neither suggested nor taught by Lloyd alone or in combination with the other references.

Docket No. CV0326

The polysiloxane of the present invention is a solvent-free adhesive. Hahn recognizes polysiloxane as a pressure sensitive adhesive. Hahn alone or in combination with the other cited references, do not teach or suggest such a solvent-free adhesive to be used as an adhesive interface between the two components of an ostomy device wherein one component has a foam surface and wherein the adhesive interface provides resistance to migration of stoma fluid and a site along which the two components are coupled and separated.

The Examiner is picking and choosing components and inappropriately combining them in support of the argument that the present invention is obvious. However, a two piece mechanical coupling (Steer), a one-piece adhesive coated foam on a pouch (Lloyd), a pressure sensitive polysiloxane adhesive (Hahn), and an adhesive composition (Doyle), do not properly suggest or teach the claimed coupleable and separable two component ostomy device having a solvent-free adhesive interface wherein the adhesive is polysiloxane and one of the two surfaces along the interface is foam.

This device provides an ostomate with a much needed two component, protective and resealable adhesively coupleable ostomy device in a manner heretofor unknown and that is surprising in its structure and operation.

Respectfully submitted,

ConvaTec Inc.
Patent Department
100 Headquarters Park Drive
Skillman, NJ 08558

Date: September 15, 2009

Stuart E. Krieger

Attorney for Applicants

Reg. No. 28,731

Phone: 908-904-2376